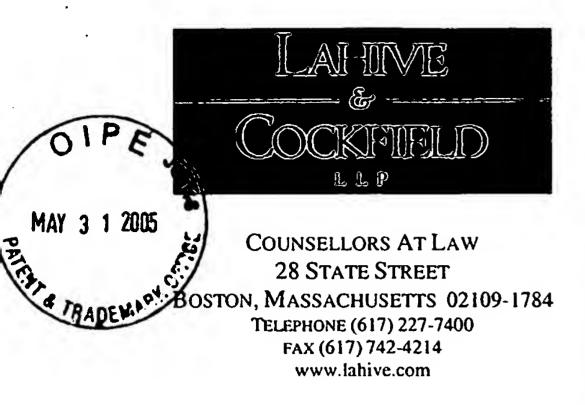
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- * Admitted in TX only
- " Admitted in CT only

May 23, 2005

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Re:

U.S. Patent Application No.: 10/602,544

For: GROWTH DIFFERENTIATION FACTOR PROMOTER AND USES

THEREFOR

Inventor: Li-Fang Liang Filed: June 23, 2003

Our Ref. No.: MTN-027DV1CN

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

- 1. Information Disclosure Statement;
- 2. **PTO Form SB/08**;
- 3. A copy of the International Search Report;
- 4. Copies of selected references cited in PTO Form SB/08 (4); and
- 5. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to:

MS Amendment, Commissioner for Patents, P.O. Box 1450,

Alexandria, Virginia 22313-1450 on:

23 May 05

Date

Jeanne M. DiGiorgio, Registration No. 41,710

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

Registration No. 41,710
Attorney for Applicant



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Li-Fang Liang

Serial No.: 10/602,544

Filed: June 23, 2003

For: GROWTH DIFFERENTATION FACTOR

PROMOTER AND USES THEREFOR

Attorney Docket No.: MTN-027DV1CN

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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23 May 05

Date of Signature and of Mail Deposit

By:

Jeanne M. DiGiorgio
Registration No. 41,710
Attorney for Applicants

Group Art Unit: 1632

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

For the Examiner's convenience in reviewing this continuation application, Applicant submits a consolidated PTO Form SB/08, listing all references cited during the prosecution of the parent application. References A6-A10, A12-B19 were previously cited and submitted to the Office in U.S. Application Serial No. 09/632,879, filed August 4, 2000 (Atty. Docket No. MTN-027DV1), of which this application is a continuation and to which this application claims priority. In accordance with 37 CFR §1.98(d), these references are not enclosed herewith, but will be provided upon request. In addition, this Information Disclosure Statement presents references A1-A5, and A11, not previously submitted to the Office, which are enclosed herewith in accordance with 37 CFR §1.97. Copies of cited U.S. patents (Reference ID Nos. A1-A2) are not enclosed with this statement. Copies of foreign patent

Serial Number: 10/602,544 Page -2- Group Art Unit: 1632

documents and non-patent literature (Reference ID Nos. A3-A5 and A11) are enclosed in accordance with 37 CFR 1.98.

Reference 5 was cited in an International Search Report dated February 25, 2000 during the prosecution of PCT/US99/16026 which corresponds to the above referenced application. A copy of the International Search Report and the cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicant understands that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted, LAHIVE & COCKFIELD, LLP

eanne M. DiGiorgio

Registration No. 41,710 Attorney for Applicants

28 State Street Boston, MA 02109 (617) 227-7400

Date: May 23, 2005

AEM/JER/JMD/JRG/rl

Enclosures

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Resoction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/B/PTO 10/602,544 **Application Number** INFORMATION DISCLOSURE June 23, 2003 Filing Date STATEMENT BY APPLICANT Li-Fang Liang First Named Inventor 1632 Art Unit (Use as many sheets as necessary) Not Yet Assigned **Examiner Name** 2 MTN-027DV1CN of Sheet 1 Attorney Docket Number

U.S. PATENT DOCUMENTS						
Examiner Initials*			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	A1	5,665,543	09-09-1997	Foulkes, et al.		
	A2	5,827,733	10-27-1998	Lee, et al.		

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	A3	WO 97/11190 A2, A3	03-27-1997	Paradign Biosciences Inc.				
	A4	9	01-13-2000	New Zealand Pastoral Agriculture Research Institute, Ltd.				
	A5	CA 2332555	01-13-2000	Bass, J., et al.				

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or T ² country where published.				
	A6	Cameron, E.R. "Recent advances in transgenic technology." <i>Mol Biotechnol</i> . 1997 Jun; 7(3):253-65.				
	A7	Crystal, R.G. "Transfer of genes to humans: early lessons and obstacles to success." Science. 1995 Oct 20; 270(5235):404-10.				
	A8	Deonarain, M.P. "Ligand-targeted receptor-mediated vectors for gene delivery." Exp. Opin. Ther. Patents. 1998; 8(1):53-69.				
	A9	Dickman, S. "Gene mutation provides more meat on the hoof." Science. 1997 Sep 26; 277(5334):1922-3.				
	A10	Eck, et al. "Gene based therapy." Goodman & Gilman's The Pharmacological Basis of Therapeutics, 9 th Edition, Chapter 5, pp. 77-101.				
	A11	Ferrell, R.E., et al. "Frequent sequence variation in the human myostatin (GDF8) gene as a marker for analysis of muscle-related phenotypes." Genomics. 1999 Dec 1; 62(2):203-7.				
	A12	GenBank Accession Number AJ133580 for Sus scrofa partial myostation gene.				
	A13	GenBank Accession Number AF093798 for Sus scrofa myostatin (gdf8) gene.				
	A14	GenBank Accession Number X24464 for Bovine myostatin genomic DNA.				

Examiner	Date	
Signature	Considered	

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Substitute for form 1449A/B/PTO				Complete if Known		
				Application Number	10/602,544	
II.	IFORMATIO	N DI	SCLOSURE	Filing Date	June 23, 2003	
S	STATEMENT BY APPLICANT			First Named Inventor	Li-Fang Liang	
				Art Unit	1632	
(Use as many sheets as necessary)			s necessary)	Examiner Name	Not Yet Assigned	
Sheet	2	of	2	Attorney Docket Number	MTN-027DV1CN	

B1	Gonzalez-Cadavid, N.F., et al. "Organization of the human myostatin gene and expression in	
	healthy men and HIV-infected men with muscle wasting." Proc Natl Acad Sci USA. 1998	
	Dec 8; 95(25):14938-43.	
B2	Grobet, L., et al. "A deletion in the bovine myostatin gene causes the double-muscled	
	phenotype in cattle." Nat Genet. 1997 Sep; 17(1):71-4.	
B3	Grobet, L., et al. "Molecular definition of an allelic series of mutations disrupting the myostatin function and causing double-muscling in cattle." Mamm Genome. 1998 Mar; 9(3):210-3.	
B4	Ji, S., et al. "Myostatin expression in porcine tissues: tissue specificity and developmental and postnatal regulation." Am J Physiol. 1998 Oct; 275(4 Pt 2):R1265-73.	
B5	Kambadur, R., et al. "Mutations in myostatin (GDF8) in double-muscled Belgian Blue and Piedmontese cattle." Genome Res. 1997 Sep; 7(9):910-6.	_
B6	McPherron, A.C., et al. "GDF-3 and GDF-9: two new members of the transforming growth factor-beta superfamily containing a novel pattern of cysteines." J Biol Chem. 1993 Feb 15; 268(5):3444-9.	
B7	McPherron, A.C., et al. "Regulation of skeletal muscle mass in mice by a new TGF-beta superfamily member." Nature. 1997 May 1; 387(6628):83-90.	
B8	McPherron, A.C., et al. "Double muscling in cattle due to mutations in the myostatin gene." Proc Natl Acad Sci USA. 1997 Nov 11; 94(23):12457-61.	
B9	Miller, N., et al. "Targeted vectors for gene therapy." FASEB J. 1995 Feb; 9(2):190-9.	
B10	Mullins, et al. "Perspectives series: Molecular medicine in genetically engineered animals." J. Clin. Invest. 98(11):S37-40.	
B11	Murch, S.H., et al. "Nutrition in inflammatory bowel disease." Baillieres Clin Gastroenterol. 1998 Dec; 12(4):719-38.	
B12	Palmiter, R.D., et al. "Germ-line transformation of mice." Annu Rev Genet. 1986; 20:465-99.	
B13	Slack, J.M. "Growth control: action mouse." Curr Biol. 1997 Aug 1; 7(8):R467-9.	
B14	Smith, T.P., et al. "Myostatin maps to the interval containing the bovine mh locus." Mamm Genome. 1997 Oct; 8(10):742-4.	
B15	Sonstegard, T.S., et al. "Refinement of bovine chromosome 2 linkage map near the mh locus reveals rearrangements between the bovine and human genomes." Anim Genet. 1998 Oct; 29(5):341-7.	
B16	Sonstegard, T.S., et al. "Myostatin maps to porcine chromosome 15 by linkage and physical analyses." Anim Genet. 1998 Feb; 29(1):19-22.	
B17	Szabo, G., et al. "A deletion in the myostatin gene causes the compact (Cmpt) hypermuscular mutation in mice." Mamm Genome. 1998 Aug; 9(8):671-2.	
B18	Verma, I.M., et al. "Gene therapy promises, problems and prospects." Nature. 1997 Sep 18; 389(6648):239-42.	
B19	Westhusin, M. "From mighty mice to mighty cows." Nat Genet. 1997 Sep; 17(1):4-5.	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date	
Signature	Considered	

^{&#}x27;Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.